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Appendix III

B.5 510(k) Premarket Notification Summary

Submitted by:	**Halozyme Therapeutics Inc 11588 Sorrento Valley Road, #17 San Diego, Ca 92121**
Contact Person:	**Mr. Don Kennard Halozyme Therapeutics Inc. 11588 Sorrento Valley Road, #17 San Diego, Ca 92121**
Trade name:	**Cumulase™ Catalog Number H4001**
Common name:	**Hyaluronidase**
Classification name:	**Reproductive Media and Supplements (21 CFR § 884.6180)**
Predicate Device:	**Medi-Cult Hyaluronidase (510(k) # K991334**
Description of the Device:	**Recombinant Human Hyaluronidase Solution**
Intended use:	**Cumulase™ is indicated for use in removing the cumulus matrix surrounding oocytes in preparation for assisted reproduction technology (ART) procedures.**
Technological Characteristics:	**Cumulase™ differs slightly from the predicate device. Specifically Cumulase™ uses a recombinant human biotechnology developed source of hyaluronidase enzymatic activity instead of a bovine testicular derived source.**

Product Formulation:

Cumulase™ is a hyaluronidase enzyme in a HEPES buffered salt solution.

The hyaluronidase enzyme raw material is a highly characterized biotechnology developed recombinant human hyaluronidase (rHuPH20).

Cumulase™ is not preserved.

Product Characterization:

rHuPH20 Hyaluronidase has been extensively characterized to International Committee on Harmonization regulatory requirements.

rHuPH20 Hyaluronidase manufacturing process media is chemically defined and is free of animal derived components or materials

Cumulase™ has been qualified to ISO 10993 standards for biocompatibility

Product Control Testing

Enzymatic Activity	USP Assay
pH	USP ‹791›
Endotoxin	USP ‹85›
Osmolality	USP ‹785›
Sterility	USP ‹71›
Mouse Embryo Assay One Cell	

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 14 2005

Mr. Don Kennard
Vice President Regulatory
and Quality Affairs
Halozyme Therapeutics, Inc.
11588 Sorrento Valley Road, Suite 17
SAN DIEGO CA 92121

Re: K042495
Trade/Device Name: Cumulase™
Regulation Number: 21 CFR 884.6180
Regulation Name: Reproductive media and supplements
Regulatory Class: II
Product Code: MQL
Dated: April 1, 2005
Received: April 4, 2005

Dear Mr. Kennard:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

C.4 Indications for Use Statement

510(k) Number (if known): K042495

Device Name: **Cumulase™**

Indications for Use: **Cumulase™ is indicated for use in removing the cumulus matrix surrounding oocytes in preparation for assisted reproduction technology (ART) procedures.**

Prescription Use ___X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Saynn

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K042495